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Responsible Conduct of Research (RCR) for Research Administrators

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Objectives:

- ❑ Identify and define core RCR areas
- ❑ Equip research administrators to be aware of RCR issues
- ❑ Generate discussion of the role of research administration with RCR

Significance of RCR?

1. Promote aims of research
2. Values are essential for collaboration
3. Provide public accountability
4. Encourage public support of research
5. Promote other moral and social values

Factors Influencing RCR

- Ethical values and actions of an investigator
- Code of ethical conduct promoted by science organizations
- Commitment to mentor young researchers
- Government regulations applicable to RCR
- Institutional processes & policies applicable to RCR

Core Areas of RCR

1. Advising & Mentoring
2. Peer Review
3. Publication & Authorship
4. Collaborative Research
5. Social Responsibility
6. Whistleblowing
7. Data Management
8. Human Subjects
9. Animal Subjects
10. Conflict of Interest
11. Research Misconduct
12. Health & Safety

1. Advising & Mentoring

Definition: someone who takes a special interest in helping another person develop into a successful researcher

Description: Experienced people sharing their knowledge; providing emotional and moral encouragement, giving specific feedback on one's performance; modeling being a ethical academic

Examples: Mentors, Advisors, Dissertation Committee Members, Clinical Directors, etc.

Advising & Mentoring (cont.)

Advisors and Mentors need to:

- Acclimate young researchers into the research community
  - *Acceptable standards and practices*
  - *Promote professional network*
- Assist young researcher in their career

Provide clear expectations

Advising & Mentoring Key Resources

Adviser, Teacher, Role Model, Friend: On Being a Mentor to Students in Science and Engineering, The 1997 National Academies handbook on mentoring. Retrieved from http://www.nap.edu/openbook.php?record_id=5789

On the Right Track: A Manual for Research Mentors (2003) is available for a fee from the Council of Graduate Schools. This manual discusses the individual and corporate responsibilities of graduate faculty in producing competent scholars capable of conducting independent, original and ethically sound research.

Mentoring International Postdocs: Working to Advance Science & Careers. An online module available from the federal Office of Research Integrity, developed by the Children's Hospital of Philadelphia, an NPA member institution.

2. Peer Review

Definition: The vetting of scientific or academic work by others working in the same field.

Description: Subjecting a scholar's work through scrutiny by other experts to ensure required standards are met within a discipline. To determine suitability of publication or for funding a research award.

Examples: Editorial boards, ad hoc reviewers, federal grant proposal reviewers

Peer Review (cont.)

- **Historical core foundation of science**
  - *Editorial boards and ad hoc reviewers (grant proposals)*

- **Responsibilities of the reviewers**:
  - Determining merit for research funding and publications
  - Impartiality
  - Privileged information and confidentiality

Peer Review (cont.)

Responsibilities of the reviewers-

- Determining merit for research funding and publications
- Impartiality
- Privileged information and confidentiality

Peer Review Key Resources

Benos, D. J., Bashari, E., Chaves, J. M., Gaggar, A., Kapoor, N., LaFrance, M., ... & Zotov, A. (2007). *The ups and downs of peer review. Advances in Physiology Education*, 31(2), 145-152.

Hames, I. (2007). *Peer Review and Manuscript Management in Scientific Journals: Guidelines for Good Practice*. Appendix I. Published Online: 26 Nov 2007. Retrieved from http://onlinelibrary.wiley.com/doi/10.1002/9780470750803.app1/pdf

Shamoo, A. E., & Resnik, D. B. (2009). *Responsible conduct of research.* Oxford University Press.

3. Publication & Authorship

Definition: An academics articles, books, and other original works

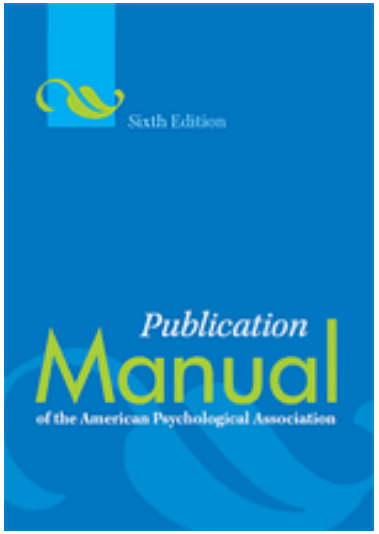
Description: The activities of preparing research findings for dissemination in a manner that ensures the integrity of the research process and fair allocation of credit

Examples: Peer-reviewed journal article publications, books, book chapter, reports, etc.

Publication & Authorship (cont.)

Elements of a Responsible Publication:

- *Abstracts*
- *Methods*
- *Results*
- *Discussion*
- *Notes, bibliography & acknowledgments*



Publication & Authorship (cont.)

ICMJE's 4 Criteria:

1. Substantial contributions (concept or design, or acquisition or analysis, interpretation of data); AND
2. Drafting/revising it critically for important intellectual content; AND
3. Final approval of the version to be published; AND
4. Agreement to be accountable for all aspects of the work

Publication & Authorship (cont.)

- "First author," normally carries the most professional prestige, important for career advancement. Therefore, deciding "first" author is potentially contentious.
- Grant PI or general supervision of the research group does not constitute authorship.
- Prestige Authorship
- Appropriate citations
- Repetitive publications, fragmentary publication.

Publication & Authorship Key Resources

Hexam, I. (2005). *Academic Plagiarism Defined*. Retrieved from http://www.ucalgary.ca/~hexham/study/plag.html.

Responsible Conduct in Collaborative Research – Overview (2005). Retrieved from http://www.niu.edu/rcrportal/collabresearch/overview/overview.html

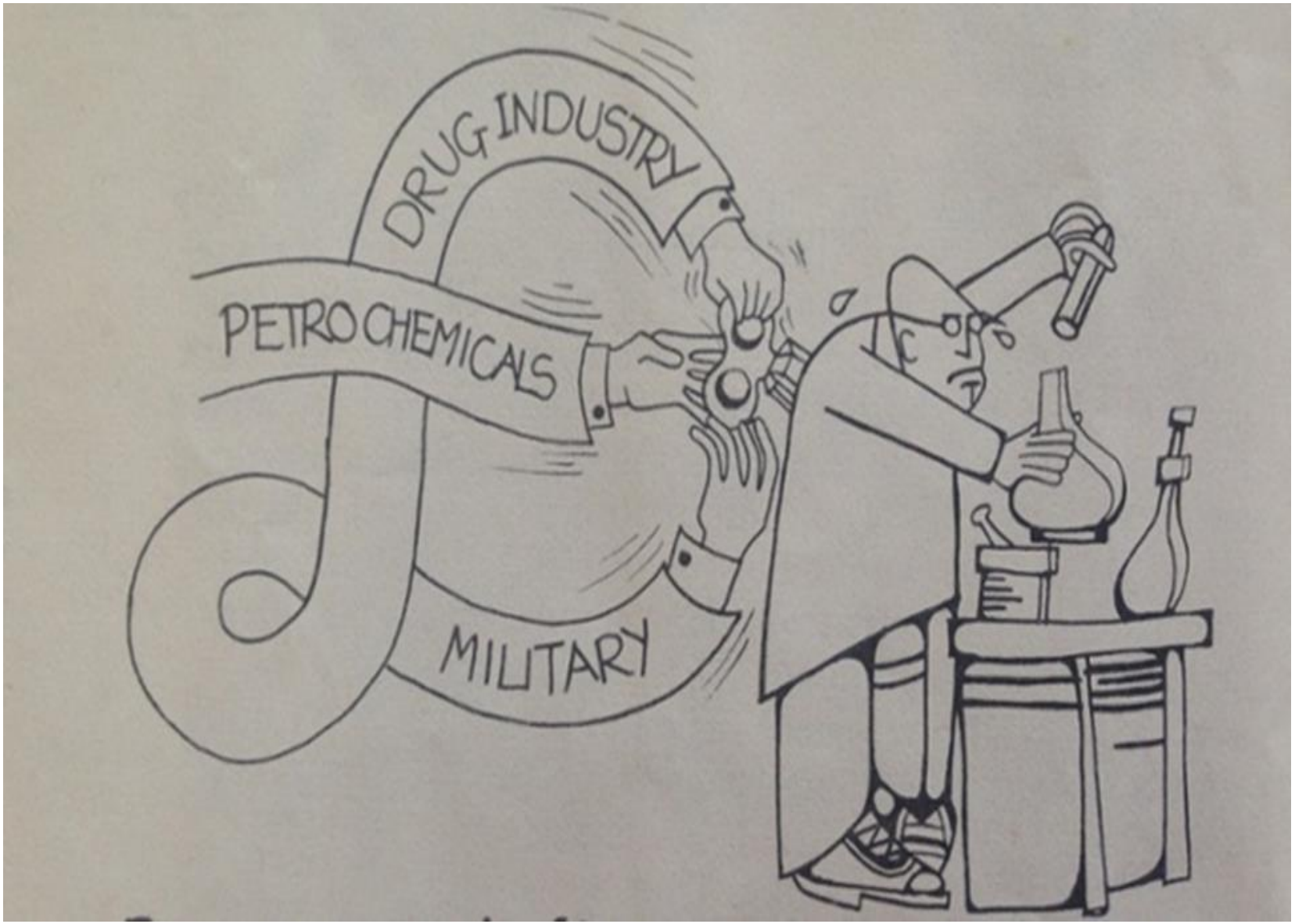
Whitbeck, C. (2005). *Responsible Authorship*. Online Ethics Center. Retrieved from http://onlineethics.org/reseth/mod/auth.html

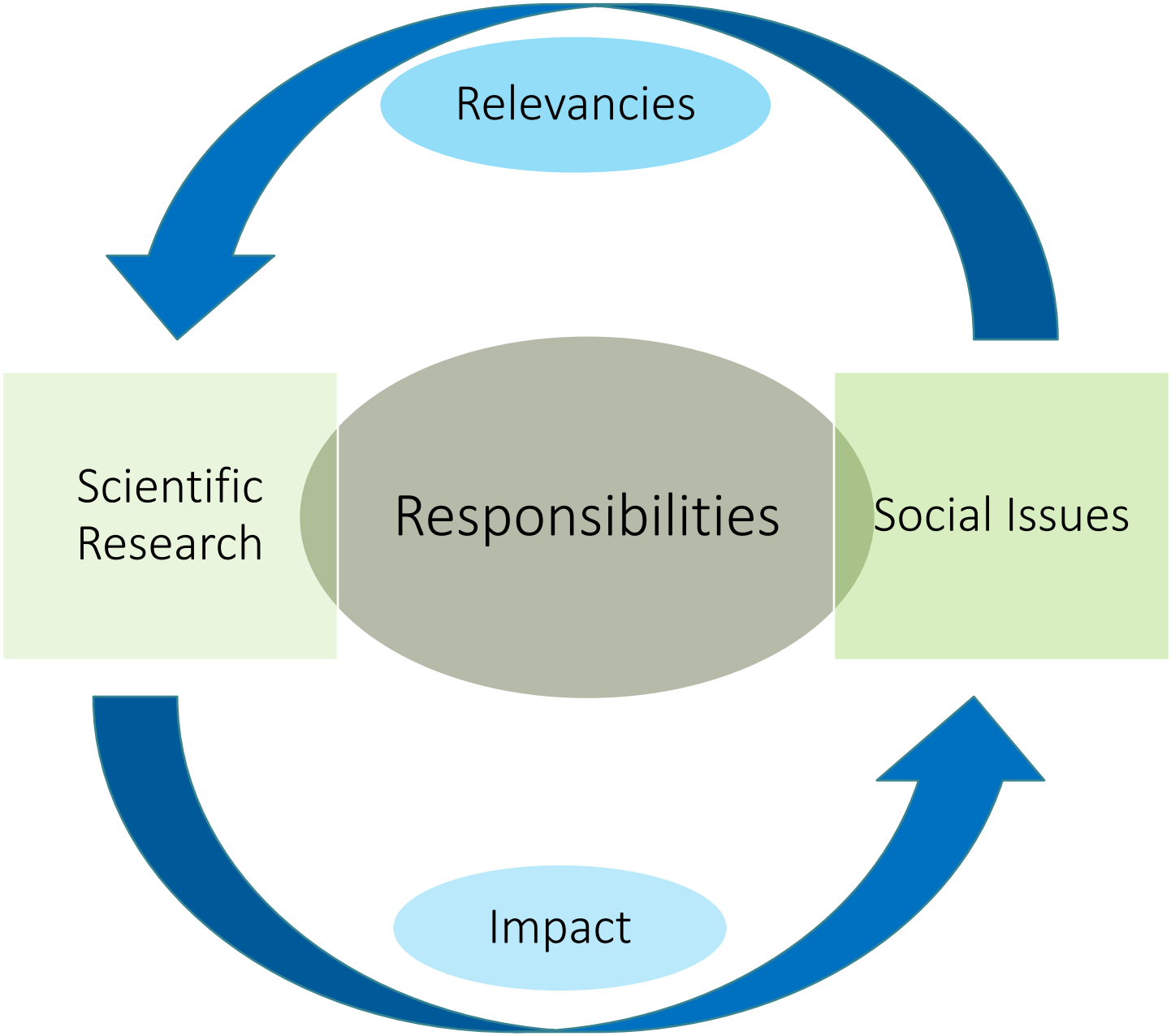
4. Social Responsibility

Definition: The relationship of researchers to the common good, to the larger society in which research is funded, conducted, and applied

Description: May covers such areas as research priorities, fiscal responsibilities, public service & education, advocacy, environmental impact, and forbidden knowledge

Example: A researcher(s) working in relatively privileged institution, may conduct research in communities burdened by environmental injustices, or science-related ethical challenges in regards to dual use technologies-used for beneficial purposes or for harmful use


DRUG INDUSTRY
PETROCHEMICALS
MILITARY



Source: http://reilly.nd.edu/research/research-integrity/social-responsibilities-for-researchers/

Social Responsibility Key Resources

Bethe H. (1983). *The ethical responsibilities of scientists: weapons development rather than military research poses the most difficult questions*. The Center Magazine. 16 (5), 2-5.

Reiser SJ & Bulger RE. (1997). The social responsibility of biological scientists. *Sci Eng Ethics. 3*(2), 137-143.

Resnik DB. (1998). *The Ethics of Science. An Introduction*, Routledge, New York, NY.

Resources for Research Ethics Education:
http://research-ethics.net/topics/social-responsibility/

Steneck N & Bulger RE. (2007). The history, purpose, and future of instruction in the responsible conduct of research. *Acad Med. 82*(9):829-834.

5. Collaborative Research

Definition: Research that involves the cooperatior researchers, institutions, organizations and/or communities, each bringing distinct expertise to a project, characterized by respectful relationships.

Description: PIs who are familiar with one another's work and collaborate on mutually beneficial research. PIs from different disciplines using a multidisciplinary approach to solve research problems. PIs from different settings (i.e. academia and industry), working jointly

Examples: Consortium, two or more researchers working together, partnerships with other institutions

Collaborative Research (cont.)

Challenges an Pitfalls:

- Uncertainty of outcomes
- A collaborator may be difficult to work with, or
- Researchers may not reach a consensus about their results
- Struggles over authorship & ownership of the research
- Differences among disciplines

Collaborative Research (cont.)

Advantages:

- Collaborative research often provides for more reliable and powerful results which allows for publication faster than independently conducted research.
- Researchers can pool their knowledge.
- Researchers can critique each other's work before starting the publication process.

Collaborative Research (cont.)

- Set ground rules early for accountability.
- Establishing critical roles and responsibilities.
- Determine authorship expectations.
- Create a data management plan for the sharing of materials and information.
- Discuss IP issues in advance.

Collaborative Research Key Resources

Collaborative Research by Northern Illinois University. Retrieved from http://ori.hhs.gov/education/products /niu_collabresearch/

Macrina, F. L. (1995). Dynamic issues in scientific integrity: Collaborative research. Washington, DC: American Academy of Microbiology. Retrieved August 20, 2005, from http://www.asm.org/ASM/files/CCLIBRARYFILES/FILENAME/0000000841/research.pdf.

Schwartz, J. P. (2011). *Silence is Not Golden: Making Collaborations Work*. NIH Catalyst. Retrieved from http://ori.dhhs.gov/silence-not-golden-making-collaborations-work

Shamoo, A. E., & Resnik, D. B. (2003). *Responsible conduct of researc*h. New York:Oxford University Press.

6. Whistleblowing

National Academy of Sciences (1995): *On Being a Scientist*.

"someone who has witnessed misconduct has an unmistakable obligation to act."

Whistleblowing (cont.)

- **Allegations of Misconduct (Whistleblowing)**
  - Necessary to protect integrity of science
  - Methods and raw data typically known only to those actually working on a project
- **Adverse Consequences**
  - The Accused
  - Whistleblower
  - Among most disruptive of events for a scientist's
    - *Career*
    - *Reputation*
    - *Productivity*

Whistleblowing Regulations/Guidelines

- Federal regulations include safeguards for informants and for the subjects of allegations, an expectation of objectivity and expertise, adherence to reasonable time limits, and respect for confidentiality.
- Whistleblower Protection Act
- Constitution, guaranteeing free speech
- False Claims Act - 15-30% of settlement

Guidelines can have as much or more importance than the regulations in reducing the chance of adverse outcomes.

Whistleblowing Key Resources

Department of Health and Human Services (2000): *Public Health Service Standards for the Protection of Research Misconduct Whistleblowers*. Notice of proposed rulemaking. Federal Register November 28, 2000 65(229):70830-70841. http://ori.hhs.gov/misconduct/nprm_reg.shtml

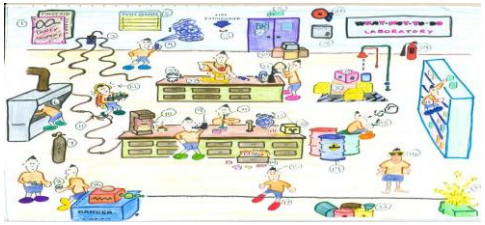
Research Triangle Institute (1995): Consequences of whistleblowing for the whistleblower in misconduct in science cases. Report submitted to Office of Research Integrity http://ori.dhhs.gov/documents/consequences.pdf

Resources for Research Ethics Education: http://research-ethics.net/topics/whistleblowing/

US Code (1986): False Claims Amendments Act of 1986. 31 USC Sections 3729-3731. http://uscode.house.gov/download/title_31.shtml

Whistleblower Protection Act of 1989. http://thomas.loc.gov/cgi-bin/query/z?c101:S.20.ENR:

7. Data Management



Definition: the method by which research data is collected, recorded, processed, organized, disseminated, stored, archived and protected.

Description:

- The importance of designing and maintaining an accurate, accessible record of a research study is relevant, as it facilitates access to sufficient detail for others to check and replicate a specific research work (i.e. laboratory notebooks/journals or electronic notebooks)
- Facilitates the validation of research findings
- Enhances research collaboration (as data is available for re-use by others)

Examples:

- Observational data
- Laboratory experimental data/journals
- Electronic notebooks
- Computer simulation data
- Textual analysis
- Digital data/text (repositories)
- Tests and databases

Young researchers/graduate students must:

- Learn and understand how to treat data. Faculty/mentors shall address this topic as relevant to RCR, and provide training in the collecting, recording, analyzing, using, storing, disclosing and sharing data.

About protection of data/privacy, confidentiality and ethical data sharing:

- In research, some data is not necessarily sharable:
  - ❖Trade secrets, commercial information
  - ❖Materials not yet published by researcher, or information which is protected under law; and
  - ❖Identifiable personnel and medical information and similar information which would constitute a invasion of personal privacy (research involving human subjects or clinical trials).

  [See *Information Privacy Act 2000; Health Records Act 2001;Freedom of Information Act 1982; Privacy Amendment (Private Sector) Act 2000*].

  - ❖Policies for data sharing - NSF, NIH, CDC, DOE, EPA, NASA, NEH, etc.

Data Management (cont.)

Examples of good data management practices:

- Back up data regularly
- Data properly maintained at institution (not at home) or with a discipline-based repository
- Data is correctly stored, as approved by institutional officials/ committees (i.e. IRB; IACUC; Special Hazards, etc.)
- Use non-proprietary data formats
- Retention of records follow federal, state, and/or institutional requirements (i.e. average 3-7 years)

Data Management Key Resources

Final NIH Statement on Sharing Research Data
http://grants.nih.gov/grants/guide/notice-files>NOT-OD-03- 021.html

Memorandum for The Heads Of Executive Departments And Agencies-Increasing Access to the Results of Federally Funded Scientific Research Office of Science and Technology Policy. February 22, 2013/
http://www.whitehourse.goc/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

PHS Office for Civil Rights – HIPAA Medical Privacy - National Standards to Protect the Privacy of Personal Health Information
http://www.hhs.gov/ocr.hipaa/

NSF Grants Policy Manual, Section 734: *Dissemination and Sharing of Research Results,* http://www.nsf.gov/pubs/manuals/gpm05_131/gpm7.jsp#734

Steneck, N.H. *Introduction to the responsible conduct of research* [Office of Research Integrity Web page]. 2004. http://ori.dhhs.gov/documents/rcrintro.pdf

8. HUMAN SUBJECT RESEARCH

DEFINITION: Human subject research (HR) is a systematic investigation involving human beings as research subjects, that can be considered research or non-research.

DESCRIPTION:

- HR can include social and behavioral activities and humanities efforts. These usually involve surveys and interviews.
- The conduct of human subject research is regulated by federal and state laws.
- All requirements of a research award involving human subject research will flow-down to all sub-recipients and other affiliates participating on the project.
- Approval by the *Institutional Review Board* (IRB) is required PRIOR to engaging in any project involving human subjects.
- The IRB is responsible for reviewing and approving the conduct of human subjects research at an institution, as its primary purpose is to secure the protection and welfare of human subjects participating in non-sponsored and sponsored programs, including clinical trials.
- The IRB has the authority to terminate the performance of a study, at any time, should a set of specific circumstances exist that can put at risk the safety and/or wellbeing of the research subjects.

Type of studies requiring IRB approval:

- Studies involving use of a drug (approved or over the counter, unless otherwise approved in the course of medical practice).
- Clinical Trials/Investigational use of marketed drugs and biologics and collection of extra biological materials.
- Studies involving use of a medical device.
- Studies requiring data submission to FDA or to be held for inspection by a regulatory agency.
- Educational surveys, interviews, tests or observations of public behavior.

Types of studies that may or may not require IRB approval:

- Classroom activities:
  - ~If there is no intention to develop or contribute to generalizable knowledge, the activity is not considered research and will not require IRB approval.
  - ~However, if it involves practice of research methodologies on human subjects, it will require IRB approval.
- Service surveys:
  - ~If intent is only to improve institutional services and/or program(s), IRB approval will not be needed.
  - ~However, if intended to produce generalizable knowledge, it will require IRB approval.
- Information gathering interviews:
  - ~Not involving research about human subjects thoughts or processes, but rather about things or products, will not require IRB approval.

ALWAYS CONTACT THE IRB OFFICE FOR ADVISE AND TO DETERMINE IF IRB REVIEW WILL BE NEEDED.

Human Subject Research Key Resources

Federal: 45 CFR Part 46

HHS Regulations for the Protection of Human Subjects
45 CFR Parts 160 and 164

Health Insurance Portability and Accountability Act (HIPAA) Regulations for Standards for Privacy of Individually Identifiable Health Information
45 CFR Part 50- Subpart F- HHS Regulations for Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

Other agencies: i.e. FDA and NSF have HR policies and procedures in place and monitoring requirements

State: Always check your "state statutes" for applicable HR requirements

Applicable Ethical Guidelines:

- ❑ Nuremberg Code
- ❑ Declaration of Helsinski
- ❑ the Belmont Report

9. ANIMAL RESEARCH

DEFINITION: **Animal research** is the use of animals in scientific research.

DESCRIPTION: Animals are used in the field of medicine and biological science:

- *To carry out tests, usually in a laboratory setting to determine, analyze and evaluate the effects of a scientific procedure(s), through experimentation or pure observation, or*
- *To test a new medicine.*

EXAMPLES: **Types of research using animals:**

- Genetic engineering (inserting, deleting or altering the function of genes)
- Military/Defense research
- Psychological research studies (i.e.: addiction experiments, alcohol dependency and withdrawal, maternal deprivation)

Usually animal research is conducted at universities, medical schools, pharmaceutical companies, farms, defense establishments and commercial facilities that provide animal testing services.

Most animals are euthanized after research experiments are completed.

Animal Research (Cont.)

Approval by the Institutional Animal Care and Use Committee (IACUC) (internal or external to the institution, as applicable) is required PRIOR to engaging in animal research for **ALL** research efforts involving animals.

Animal Research Key References

~ Animal Welfare Act (1996)
http://constitution.laws.com/animal-welfare-act

~ Title 9:Code of Federal Regulations, Chapter 1, SubChapter A: Animal Welfare
http://www.ecfr.gov/cgi-bin/textidx?tpl=/ecfrbrowse/Title09/9cfrv1_02.tpl

~ U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
http://grants.nih.gov/grants/olaw/tutorial/relevant.htm

~ NIH Policy- Office of Laboratory Animal Welfare (OLAW)
http://bioethics.od.nih.gov/animals.html

~ PHS Policy on Humane Care and Use of Laboratory Animals
http://www.grants.nih.gov/grants/olaw/references/phspol.htm#PublicHealthServicePolicyonHumaneCareandUseofLaboratory

~ Guide for the Care and Use of Laboratory Animals (The Guide, NCR 2011)
http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf

~ Guide for the Care and Use of Agricultural Animals in Research and Teaching (the Ag Guide, FASS 2010) http://www.fass.org/page.asp?pageID=216&autotry=true&ULnotkn=true

~ European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123)
http://www.conventions.coe.int/Treaty/en/Treaties/Html/123.htm

Animal Research Key Resources

- Animal Welfare Act (1996)
  http://constitution.laws.com/animal-welfare-act
- Title 9:Code of Federal Regulations, Chapter 1, SubChapter A: Animal Welfare
  http://www.ecfr.gov/cgi-bin/text- idx?tpl=/ecfrbrowse/Title09/9cfrv1_02.tpl
- U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training
  http://grants.nih.gov/grants/olaw/tutorial/relevant.htm
- NIH Policy- Office of Laboratory Animal Welfare (OLAW)
  http://bioethics.od.nih.gov/animals.html
- PHS Policy on Humane Care and Use of Laboratory Animals
  http://www.grants.nih.gov/grants/olaw/references/phspol.htm#PublicHealth ServicePolicyonHumaneCareandUseofLaboratory
- Guide for the Care and Use of Laboratory Animals (The Guide, NCR 2011)
  http://grants.nih.gov/grants/olaw/Guide-for-the-Care-and-Use-of-Laboratory-Animals.pdf
- Guide for the Care and Use of Agricultural Animals in Research and Teaching (the Ag Guide, FASS 2010)
  http://www.fass.org/page.asp?pageID=216&autotry=true&ULnotkn=true
- European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (ETS 123)
  http://www.conventions.coe.int/Treaty/en/Treaties/Html/123.htm

10. CONFLICT OF INTEREST (COI)

DEFINITION: What is a COI?

Any conflict between the private (financial) interests of the employee and the public interest of the university, when such interest has the potential to undermine the employee's professional performance and objectivity relating to his/her institutional responsibilities, and/or to the design, conduct or reporting of research.

42 CFR Parts 50 & 94 (revised August 2011) defines what is a Significant Financial Interest for purposes of PHS funded research.

Examples of COI:

- Ownership or Equity: Employee's involvement in a procurement/purchasing decision involving an entity responsible for the distribution and marketing of a specified product (including medical) and where the employee has ownership and/or a financial interest in the such entity.
- Consulting: A consulting relationship with an entity owned by an employee or where employee holds equity, when the entity is sponsoring the employee's research at his/her institution, or when intellectual property transactions exist between the university and the entity.

COI & COC Disclosure submission:

- Employees are required to disclose their outside activities and potential conflict of interests to the university on an annual basis.
- Employees participating in research projects sponsored by DHHS/PHS/NIH and other agencies that adopted the Financial Conflict of federal regulation, who are responsible for design, conduct or reporting of research (DCR) must submit an annual disclosure upon request by the university.
- University reviewers will assess disclosed outside activities and potential conflict of interests actions reported by the employees and determine if any of such activities require monitoring or mitigation efforts by the university.
- Several conflicts can be managed through the granting of an exemption if allowed under state statutes. However, each university shall review its statutory requirements as they relate to potential conflict of interest, as they differ from state to state. Some states will not allow the granting of exemptions relating to an identified conflict of interest.

CONFLICTS OF COMMITMENT (COC)

What is a COC?

Any outside activity (compensated or uncompensated) that involves frequent or prolonged absences of an employee due to an engagement(s) in non-institutional business, at times when the employee is expected to be engaged in the performance of institutional responsibilities.

Examples:

- **Consulting**

  Employee uses time and/or resources from institution in furtherance of his/her private consulting or outside business activities

- **Private practice efforts**

  Employee engages in a decision at the institution that affects a grant/contract between the institution and an entity (private practice) for which the individual holds a position/ appointment and personal interest.

- **Additional teaching or research (i.e. Dual Compensation)**

COI & COC Key Resources

~ TITLE 42 CFR Part 50

Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors/Final Rule (August 25, 2011; Effective August 24, 2012) http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf

~ State statutes (for regulatory requirements)

[In Florida]:
Title X, Chapter 112. Code of Ethics for Public Officers and Employees (SS. 112.311- 112.3261)
http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_Strin g=&URL=0100-0199/0112/0112PARTIIIContentsIndex.html

11. RESEARCH MISCONDUCT

Definition:

42 CFR Part 93 defines research misconduct (RM) as *Fabrication, Falsification, or Plagiarism* in proposing, performing, or reviewing research, or in reporting research results.

Institutions must have policies and procedures in place to handle *Assessments, Inquiries or Investigations* of allegations of research misconduct, to determine if an allegation is substantiated or not.

Related Definitions- RM terms

Fabrication is making up data or results and recording or reporting them.

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research Misconduct does NOT include honest errors or differences of opinion.

Intent is important

Research Misconduct (Cont.)

Examples:

- **Fabrication:**

  i.e. Making up data (including patient data) that does not exist; generate records for non-real subjects; making up research results and reporting them to a sponsor; inclusion of numbers and statistical results resulting from a proposed experiment where significant portions of the experiment were never performed, but were however, fully described in the research results section of the research report submitted to a sponsor.

- **Falsification:**

  i.e.: Alteration of data, dates, digital pictures (figures) and results of particular tests; representing past contacts as current, changing results of blood tests; changing or omitting results or data which makes research not accurately represented in the research record.

- **Plagiarism:**

  i.e.: Use of portions of material from published journals and/or documents available through internet as part of the methodology section of a research proposal submitted to a sponsor, without providing citations (references). This action will mislead the reader/reviewer into thinking that such material was original to the investigator.

Review of an allegation of Research Misconduct

Allegation review and processing:

- Sponsor can initiate review
- Sponsor can ask university to conduct investigation
- University can initiate review, or complete review of a sponsor-initiated review action.

Roles:

Complainant= Person making an allegation of research misconduct

Respondent= Person accused of research misconduct

University= Has an RM Policy and Assurance in place that defines allegation review procedures; conducts review, prepares and submits report of findings to the sponsor or the Complainant (as applicable); and if the allegation is not confirmed, diligently restores Respondent's reputation.

RM review phases:

Assessment

[The institutional RIO leads the Assessment process and determines if the preponderance of the evidence warrants an Inquiry. If not, the process ends at this stage].

Inquiry

[A small committee of peers is appointed by the institutional *Deciding Official* to review results of the Assessment process and determine if a full investigation is warranted. If not, the process ends at this stage].

Investigation

[A larger committee of peers (usually 5 members) is appointed by the Deciding Official to review the facts of the allegation and the results of the Assessment and Inquiry process; The committee reports its determination to the RIO on whether the allegation was founded and recommends pertinent administrative actions].

Basic considerations (among others) during the allegation review process

- Does the allegation falls within the federal definition of research misconduct, or is it another type of misconduct action that should be reviewed by another unit of the institution (i.e. audit office) instead of the sponsored programs office)?

- Does the evidence provided by the Complainant substantiates the allegation of research misconduct (is it sufficiently credible, easily identifiable)?

- Was this action done knowingly or unknowingly?

- What is the level of intent?

[*Careless; Reckless (grossly negligent); Knowing, or Intentional/Purposeful*]

12. Health & Safety



Definition: Assessment of risk in regards to biosafety occupational health in research laboratories

Description: Ensure those conducting research activities potentially exposed to hazardous materials/ agents are offered the best possible information regarding those hazards, laboratory procedures, safety equipment, and access to medicine services and providers

Examples: Biological agents/Pathogens, bacteria, toxins, viruses, radioactive material, recombinant DNA, etc.

Health & Safety (Cont.)

Considerations:

- Safe handling & disposal of materials in laboratories
- Safe operation of equipment
- Safety management and accountability
- Hazard assessment processes
- Safe transportation of materials between laboratories
- Safe design of facilities
- Emergency response plans
- Environmental safety plans
- Safety education of all personnel before entering the laboratory

Health & Safety (Cont.)

❖Health and Safety standards in the lab are federally regulated.

❖ROLES:

- The institution is responsible for providing a safe and healthy laboratory environment to investigators, research staff and any other employee having access to the lab.
- Investigators must understand the potential risks associated to the use, handling and disposal of material inherent to a sponsored activity, which are considered to be hazardous to an individual's health or to the work environment.
- The institution's Health and Safety Office must provide safety standards policies and procedures, manuals addressing the use, handling and disposal of biological agents, recombinant DNA, infectious or bio hazardous agents and radioactive materials.. Different safety standards apply to different scientific disciplines. Safety emergency plans must also be available at each lab [in case of an emergency, who does what, and how].
- The Health and Safety Office staff is responsible for the monitoring and oversight of laboratories located at institutional facilities and related safety plans shall be provided y to investigators, including the review and implementation of environmental health and/or safety plans required by a sponsor in support a sponsored activity involving any type of special hazards.

❖TRAINING on health and safety issues must be provided to all research personnel, including students.

❖Laboratory Notes [Although not necessarily related to the physical handling of material in the lab, investigators shall also focus on the importance of laboratory notebooks (written or in an electronic format). These tools, addition to capturing what the National Institutes of Health (NIH) defines as "data," will also document the use, handling and disposal procedures used by the researcher during an experiment or procedure. These notes could be used as documentation for verification of research results and/or any investigation resulting from an allegation of falsification or fabrication of research results, as well as for the review of an occurrence of an adverse event during implementation of an experiment or procedure].

Health & Safety Key Resources

Regulatory Documents

~Commerce Control List for Exports (Biological Agents and Toxins) (PDF)

~*Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition, CDC / NIH (http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf)

~*NIH Guidelines* for Research Involving Recombinant DNA Molecules

For the full text of *NIH Guidelines* (PDF)

~Title 29 CFR Labor- Regulations-Standards

http://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title29/29tab_02.tpl

~*Occupational Safety & Health Administration (OSHA)/ United States Department of Labor*

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106

~Clean Water Act

http://www2.epa.gov/laws-regulations

~Toxic Substances Control Act

http://www2.epa.gov/laws-regulations

~Resource Conservation and Recovery Act (2006)

http://www.epa.gov/epawaste/laws-regs/rcraguidance.htm

~Federal Facility Compliance Act

http://www2.epa.gov/fedfac

❖Also check your institutional Health & Safety policies and procedures

[In Florida: Florida Administrative Code; Florida Statues-Chapter 624 (Insurance Code) and Chapter 284 (Public Business State Risk Management and Safety Programs)]

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